## REMARKS / ARGUMENTS

Claims 3-5, 7-10, 17 and 25-34 were pending in the above-captioned patent application at the time of the Office Action and all stand rejected. In response to the rejections, applicant retains all of the above-recited pending claims and adds new claims 35-38.

Each specific ground of rejection is addressed below.

**New Claims**

New claims 35-38 are added which are essentially identical to previously presented claims 25-28 before these claims were amended on April 2, 2003, to include additional limitations with respect to the pump flowpath. Although applicant amended claims 25-28 to avoid prior art, applicant wishes to maintain claims pending which correspond to claims 25-28 before the amendment. By doing so, applicant preserves the issue of patentability of claims 35-38 should an appeal of a final rejection be necessary.

New claims 35-38 are believed allowable for the reasons set forth in the amendment of November 14, 2002, which are reiterated as follows. U.S. Patent 4,623,338 to Laby et al. teaches a medication delivery system comprising an infusion pump including a fluid storage chamber, a displacement piston, an elastic member and a pump outlet. However, Laby et al. lacks teaching of a bolus injector as recited in applicant's claims 25 and 26. Laby et al. further lacks teaching of a drip chamber as recited in applicant's claims 1, 2, 6-8. Accordingly, U.S. Patent 5,505,707Manzie et al. is cited for its teaching of a bolus injector and a drip chamber. The Examiner has asserted that applicant's invention recited in claims 1-10 and 25-26 is an unpatentably obvious combination derived from the teaching of Laby et al. and Manzie et al.

It is well settled that a finding of obviousness requires a suggestion or motivation in the prior art whereby one of ordinary skill in the art would have combined the prior art teaching to arrive at the claimed invention. *C.R. Bard Inc. v. M3 Sys. Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998). The Examiner has relied on column 1, lines 45-50, of Manzie et al.

to provide the requisite motivation for combining the teaching of the two references, i.e., Laby et al. and Manzie et al., in the manner of the claimed invention. Manzie et al. states therein that prior art systems for delivering irrigating fluid to a surgical site have several disadvantages. Specifically, "it may be inconvenient or awkward for the physician to adjust the clamp to control the flow [of water] while also handling the surgical instrument. In addition, the volume and pressure of water being delivered may be difficult to control." Manzie et al. continues this discussion at col. 1, lines 51-54, "Accordingly, it is an object of the present invention [i.e., the disclosed invention of Manzie et al.] to provide a system and method that addresses or overcomes the disadvantages of the prior methods of fluid delivery to an internal body site."

From the above quoted passages of Manzie et al., it is apparent that the disclosed fluid delivery system of Manzie et al. avoids the problems of prior art fluid delivery systems. In particular, it is relatively convenient for the physician to simultaneously control the flow of water and handle the surgical instrument when using the fluid delivery system of Manzie et al. It is also relatively easy for the physician to control the volume and pressure of water delivery when using the fluid delivery system of Manzie et al. Manzie et al. overcomes the problems of prior art fluid delivery systems despite the fact that the fluid delivery system disclosed in Manzie et al. lacks an infusion pump which includes a fluid storage chamber, a displacement piston, an elastic member and a pump outlet.

In sum, Manzie et al. teaches one of ordinary skill in the art that a fluid delivery system can operate effectively with simply a gravity driven fluid storage chamber, a drip chamber and a bolus injector. A spring driven infusion pump is neither required nor desired for effective operation of a fluid delivery system having a bolus injector under the teaching of Manzie et al. Accordingly, it cannot be said that the teaching of Manzie et al. provides the requisite motivation for combining an infusion pump with a bolus injector in a fluid delivery system as applicant's have claimed. In the absence of such motivation, the obviousness rejection is unsupported and applicant respectfully requests its withdrawal.

**Rejections Under 35 U.S.C. §103**

Claims 3-5, 7-10, 25, 26 and 29-34 have been rejected under 35 U.S.C. §103(a) as being unpatentably obvious over U.S. Patent 4,623,330 to Laby et al. in view of U.S. Patent 5,505,707 to Manzie et al. Pending independent claims 25, 26, and 29 recite a pump flowpath providing fluid communication between a fluid storage chamber and a pump outlet. The pump flowpath has a flow restriction and a drip chamber. The flow restriction is sized to convert a continuous stream of a fluid entering the flow restriction from the fluid storage chamber to a drip stream exiting the flow restriction into the drip chamber. The drip chamber has a drip chamber wall, an upper portion, and a lower portion. An outlet tube is positioned beneath the flow restriction in the lower portion and extends toward the upper portion. The outlet tube has a smaller cross section than the drip chamber to define a fluid accumulation space between the outlet tube and the drip chamber wall where at least some of said fluid exiting the flow restriction into the drip chamber accumulates.

The Office Action asserts at page 4 that Manzie et al. discloses the claimed flow restriction and drip chamber. In particular, the Office Action asserts that the structural element shown and designated as 158 in Figure 2 and described at col. 5, lines 51-56 of Manzie et al. reads on the claimed flow restriction and drip chamber. The Office Action states:

> "In figure 2, a flow restriction and a drip chamber 158, the drip chamber has an upper and a lower portion. An outlet tube (located in the area 158 is pointing in figure 2) is positioned beneath the flow restriction in the lower portion of the drip chamber and extending towards the upper portion, the outlet tube has a smaller cross section than the drip chamber."

It is respectfully submitted that the Office Action incorrectly characterizes the structural element 158 of Manzie et al. as a drip chamber and further that the Office Action improperly reads the structural element 158 on applicant's claimed drip chamber. The structural element 158 of Manzie et al. shown in the embodiment of Figure 2 is termed a "second valve" (col. 5, line 41) and is described as preferably being identical to a first valve

135 (col. 5, lines 46) also shown in the embodiment of Figure 2. The first valve 135 is described at col. 5, lines 40-50. A preferred embodiment of the first valve 135 is a commercially available pillow valve available from Haemotronic. It is noted that no alternate embodiments of the first and second valves 135, 158 are described or suggested in Manzie et al.

An "Exhibit A" is enclosed with the instant response which is a current print out of a page from Haemotronic's website showing representative welded pillow valves of the type shown and described in Manzie et al. Attention is drawn to the pillow valve designated PP/3 in Exhibit A. Applicant has red-lined the boundary of the valve chamber and blue-lined the boundary of the welds of the PP/3 pillow valve. An "Exhibit B" is also enclosed with the instant response which is copy of drawing sheet 2 of Manzie et al. displaying Figure 2. Applicant has similarly red-lined the boundary of the valve chamber and blue-lined the boundary of the welds of the second valve 158 in Figure 2.

A pillow valve is a one-way valve typically constructed from a short segment of soft readily-collapsible plastic tubing having an open upper end and an open lower end. An inlet tube of a more rigid (i.e., less readily-collapsible) narrower tubing is placed in the wider open upper end of the soft tubing segment and an outlet tube substantially identical to the inlet tube is placed in the wider open lower end of the soft tubing segment. The open upper and lower ends of the tubing segment with the inlet and outlet tubes positioned therein are then welded together to seal the ends shut around the inlet and outlet tubes, respectively, and form a valve chamber of a given volume between the welds. The weld at the upper end of the valve 158 is a flat tab which holds the inlet tube in place at the top of the valve chamber. Similarly, the weld at the lower end of the valve 158 is a flat tab which holds the outlet tube in place at the bottom of the valve chamber.

It is apparent from the shading on the valve chamber of the valve 158 of Figure 2 that the valve chamber is a three-dimensional enclosure having a defined volume. It is likewise apparent from the absence of shading on the upper and lower welds of the valve 158 of Figure 2 that each weld is a two-dimensional sheet having essentially no volume

except for the portion wrapping around the inlet or outlet tube. The inlet tube of the valve 158 has a "duck bill" which extends into the upper portion of the valve chamber and functions as a flow restriction. However, the outlet tube of the valve 158 terminates at the weld at the lower end of the valve and does not extend into the lower portion of the valve chamber. Thus, the valve 158 of Manzie et al. does not read on the claimed drip chamber because **the outlet tube of the valve 158 is not positioned in the lower portion of the chamber**, as required by applicant's claims, but only extends as far as the weld beneath the chamber. As a result, the outlet tube of the valve 158 does not define a fluid accumulation space between the outlet tube and the chamber wall, as further required by applicant's claims, where at least some of said fluid exiting the flow restriction into the chamber accumulates.

This distinction is significant because applicant's claimed infusion pump configuration enables advantageous operation not disclosed in the prior art of record. In particular, if the infusion pump is inadvertently overturned during user activity, the configuration of the inverted drip chamber nevertheless maintains the ratio of air to liquid in the drip chamber constant by trapping an air pocket in the fluid accumulation space. Therefore, fluid medication cannot drain back into the drip chamber via the outlet tube because it is unable to displace the air pocket out the inlet end. If the drip chamber were configured in the manner of the valve 158 of Manzie et al., the entire drip chamber could fill with fluid medication upon inversion and remain in the drip chamber even after the drip chamber is restored to its upright position. If the drip chamber is filled in its entirety with fluid medication, the user is unable to visually detect fluid flow through the drip chamber.

Applicant acknowledges that the operational characteristics of the infusion pump recited in the preceding paragraph are not claim limitations, which distinguish applicant's claimed structure over the cited prior art. Nevertheless, the preceding paragraph is relevant to the issue of non-obviousness. Structural distinctions between the applicant's claimed apparatus and the cited prior art apparatus, which enable the claimed apparatus to operate in a manner not recognized by the cited prior art, support a finding that the

claimed structure is patentably non-obvious over the prior art.

Applicant further acknowledges one could argue that the disclosure of Manzie et al. with respect to the structural element 158 is not limited to the preferred embodiment disclosed in the specification of Manzie et al. (i.e., pillow valves), but may more broadly suggest other one-way valves known to one of ordinary skill in the art. Applicant does not agree with this argument. However, even if the premise of this argument is assumed correct for the sake of discussion, Manzie et al. must still suggest a one-way valve having a structure specifically resembling the claimed structure of applicant's flow restriction and drip chamber to support the instant rejection, which Manzie et al. fails to do.

It is also noted that one-way valves, such as pillow valves, are not considered by one of ordinary skill in the art to be analogous or equivalent to a drip chamber. This is evidenced by the hierarchical product listing of Exhibit A where pillow valves are listed under the heading "adaptors and clamps", while drip chambers are listed under their own separate heading "drip chambers and spikes". Finally, there is nothing in the disclosure of Manzie et al. to suggest that a one-way valve includes any structure other than that necessary to perform the function of enabling uni-directional flow and preventing bi-directional flow through the valve. Manzie et al. is devoid of any disclosure of a one-way valve having structure for converting a continuous fluid stream to a drip stream which is a requirement of the claimed flow restriction.

The structural element 60 of Manzie et al. shown in the embodiment of Figure 2 is termed a "tubing clamp" (col. 3, line 66 - col. 4, line 6) and is described as having an adjustable flow restriction function which enables the user to reduce the flow rate of fluid through the tubing section 40 downstream of the clamp 60 to a relatively low rate, e.g., a trickle, which may be characterized as a drip stream (col. 4, lines 31-42). Although the clamp 60 has structure for converting a continuous fluid stream to a drip stream, there is no disclosure or suggestion in Manzie et al. to substitute the clamp 60 for the claimed flow restriction of applicant's claimed infusion pump in a manner which would render applicant's infusion pump unpatentably obvious. Furthermore, it is apparent that the clamp 60 lacks

structure, which would read on or suggest the specific structure of the claimed drip chamber and which provides the additional advantages described above that are not recognized in the prior art.

The structural element 413 of Manzie et al. shown in the embodiment of Figure 6 is termed a "flow chamber" (col. 8, lines 32-33) and is described as having a sight function which enables the user to observe the fluid dripping in the flow chamber 413 (col. 8, lines 42-46). Although the flow chamber 413 has structure for viewing a drip stream therein, there is no disclosure or suggestion in Manzie et al. to substitute the flow chamber 413 for the claimed drip chamber of applicant's claimed infusion pump in a manner which would render applicant's infusion pump unpatentably obvious. Furthermore, there is no disclosure of the specific internal structure of the flow chamber 413, which would read on or suggest the specific structure of the claimed drip chamber and which provides the additional advantages described above that are not recognized in the prior art.

For the reasons set forth above, it is respectfully submitted that pending independent claims 25, 26, and 29 and their pending dependent claims 3-5, 7-10, and 30-34 traverse the instant ground of rejection.

Dependent claim 30 traverses the instant ground of rejection for the additional reason that the valve 158 of Manzie et al. fails to disclose positioning the inlet end of the outlet tube approximately at the volumetric center of the drip chamber. Dependent claims 31-34 traverse the instant ground of rejection for the additional reason that the valve 158 of Manzie et al. fails to disclose an outlet tube in the chamber which is configured to revert the drip stream exiting the flow restriction to a reverted continuous stream.

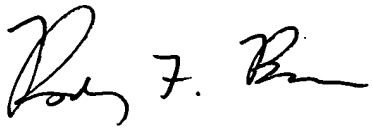
Claims 17, 27, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentably obvious over U.S. Patent 6,247,995 to Bryan in view of U.S. Patent 5,505,707 to Manzie et al. It is respectfully submitted that claims 17, 27, and 28 traverse the instant ground of rejection for substantially the same reasons as set forth above with respect to claims 25, 26, and 29. Bryan fails to supplement the teaching of Manzie et al. with respect to the flow restriction and drip chamber in the pump flowpath.

The remaining prior art references made of record and not relied upon have been considered by applicant, but are not deemed sufficient to render the instant pending claims unpatentably obvious.

**Conclusion**

In conclusion, applicant respectfully asserts that all pending claims 3-5, 7-10, 17 and 25-38 in the instant patent application are allowable for the reasons set forth above. Accordingly, an early notice of allowance is earnestly solicited. The Examiner is requested to call the undersigned at (858) 272-8705 for any reason that would advance the instant application to issue.

Respectfully submitted,



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enclosures: Exhibit A
Exhibit B